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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,625	06/27/2003	Shelby L. Cook	022956-0214	9377
21125 7590 05/28/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER NGUYEN, TUAN VAN	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 05/28/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/615,625	<b>Applicant(s)</b> COOK ET AL.	
	<b>Examiner</b> TUAN V. NGUYEN	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-5 and 8-19 are pending. These claims were examined and rejected in the Office Action mailed out on 01/04/2010.

#### ***Reopening of Prosecution After Appeal***

2. In view of the appeal brief filed on February 26, 2010, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below:

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or, (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/ (Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773

***Response to Arguments***

3. Applicant's arguments in the appeal brief with respect to the rejection of claims 1-5 and 8-19 under 35 U.S.C. 103(a) as unpatentable over Pedlick et al. (U.S. 6,270,518) in view of Barlett (US 5,626,612) have been fully considered and persuasive. Therefore, the rejection has been withdrawn.
4. A Declaration establishes that the Applicant invented and reduced to practice the subject matter as claimed in this present application prior to June 02, 2003, which is the effective date of Haut et al. (US 7,320,701). Therefore, the rejections have been withdrawn.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Line 2 recites the limitation of "symmetry", however, the specification fails to disclose this limitation. Lines 8-11 discloses the limitation of "the suture channel extending between the two opposed

surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion", however, the specification fails to disclose the underline limitations above.

7. Turning to the specification and drawings for guidance, one finds, "a suture channel 32 for passage of a suture strand through the suture anchor. As shown in FIG. 2B, the suture channel 32 extends in a direction transverse to the longitudinal axis L of the elongate body 12 and through each of the opposed surfaces 20 of suture anchor 10... As illustrated in FIG. 2A, a center of the opening 34 is longitudinally offset with respect to the longitudinal axis L on the side of the axis opposite the flared portion 24" (see page 5, line 26 to page 6, line 9 and Fig. 2B). Noting that "axis of symmetry" is defined as an imaginary line that is located in a symmetric plane that bisected a component into two identical parts or components. For examination purpose, Examiner interprets the limitation above, in view of the specification, as the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, **wherein the longitudinal axis of symmetry is the axis L as shown in Fig. 2B of the present application**, and a **center of an opening of the suture channel** having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body, **wherein the**

**axis of symmetry is the axis L as shown in Fig. 2B of the present application,**  
in a direction opposite to the direction of the flared portion.

8. Claims 2-5, 8-14 are rejected for the same reason as claim 1 by the virtue of dependency on claim 1.
9. Claim 15 and its dependent claims are rejected for the same reasons as claim 1.
10. Claim 19 is rejected for the same reason as claim 1.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 1, 4, 5, 8-13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedlick et al. (U.S. 6,270,518).**
13. For example, Pedlick discloses (see Figs. 35-36 and 38-41) a bioabsorbable suture anchor 301 for anchoring tissue to a bone, comprising: an elongate body 310 defined by a longitudinal axis; a first, leading end 302, includes a rounded distal end 304, and a second, trailing end 306; the elongate body comprising two opposed surfaces 320 between the first and second ends, and a plurality of sidewalls 312, 316 extending between the two opposed surfaces; a flared portion 308, includes biting edge 322 formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone

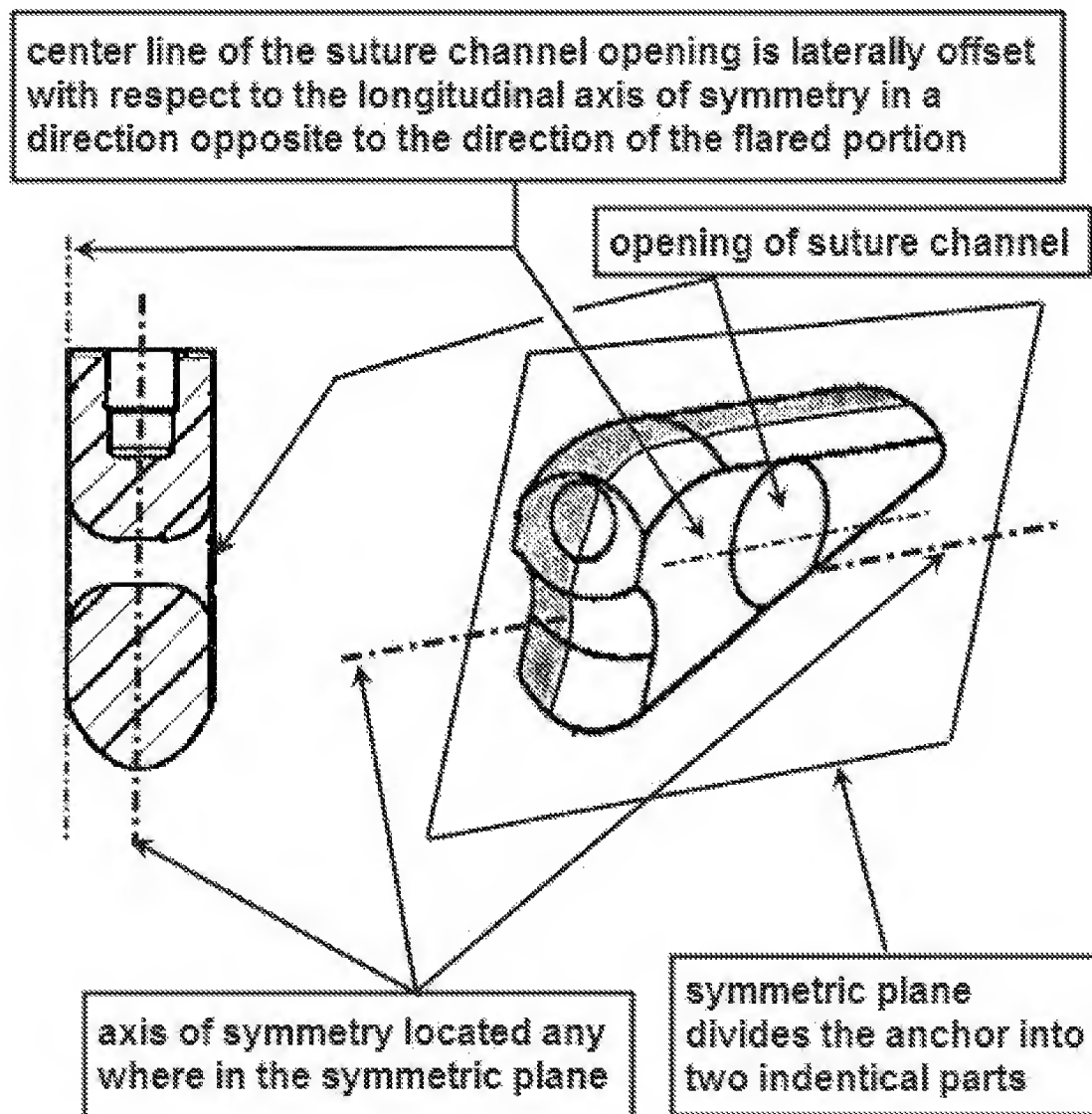
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tissue; and a suture channel 330, that includes rounded edge 330 on both sides, formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, and strand of suture is inserted through the channel, and the center of the channel is offset from the longitudinal axis of the anchor (see Fig. 41); and the anchor also includes a blind hole 334 for engaging with insertion tool (see Fig. 36), wherein the insertion tool having elongate member with a proximal, handle end and a distal, attachment end (see col. 14, lines 1–60).

14. With respect to the limitation of “the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion”, Examiner interprets the limitation above, in view of the specification, as the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, **wherein the axis of symmetry is the axis L as shown in Fig. 2B of the present application**, and **a center of an opening of the suture channel** having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body, **wherein the axis of symmetry is the axis L as shown in Fig. 2B of the present application**, in a direction opposite to the direction of the flared portion. Figures 37 and 39 of Peddlick's drawings, reproduced and annotated below, show the axis of symmetry

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is positioned anywhere in a plane that bisects the anchor 300 as shown in the annotated figure below into two identical parts and the center axis that is passed through the suture channel opening 330, which is located on the surface 320 (see Fig. 40), is laterally offset with respect to the longitudinal axis of symmetry (see annotated figure) and in a direction opposite to the direction of the flared portion (see annotated figure).





***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. **Claims 2, 3, 14, 17, and 18 are rejected under 35 U.S.C. 103(a) as unpatentable over Pedlick et al. (U.S. 6,270,518).**

18. Regarding claim 2 and 17, Pedlick discloses the invention substantially as claimed except for disclosing the length of the elongate body is in the range of about 2 to about 6 mm. Noting that Pedlick discloses the overall size of the suture anchor is about 3 mm (Col. 9: 23-25), thus, Pedlick inherently discloses the length, the width and the thickness of the anchor are the effective variables to establish the overall

size of the anchor. It would have been obvious to one of ordinary skill in the art to design the length of the elongate body of the anchor as disclosed by Pedlick in the range of about 2 to about 6 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

19. Regarding claim 3 and 18, Pedlick discloses the invention substantially as claimed except for disclosing the width of the second trailing end is about 1 to about 3 mm at its widest point. Noting that Pedlick discloses the overall size of the suture anchor is about 3 mm (Col. 9: 23-25), thus, Pedlick inherently discloses the length, the width and the thickness of the anchor are the effective variables to establish the overall size of the anchor. It would have been obvious to one of ordinary skill in the art to design the width of the second trailing end at the widest point of the anchor as disclosed by Pedlick in the range of about 1 to about 3 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.
20. Regarding claim 14, Pedlick discloses the invention substantially as claimed except for disclosing the elongate body is formed with a blue dye. Pedlick discloses the suture anchor is made from stainless steel and polymer. Pedlick further discloses when the procedure requires more than one suture anchor, to improve suture and anchor management, it may be desired to mark various suture lengths and anchor with color-coded (Col. 20: 42-61). It is old and well known that

color such as yellow, red, and blue enhancing the ability of visual recognition to the human eye. It would have been obvious to one of ordinary skill in the art to use blue dye to cover the nature color of the stainless steel and polymer because the blue color would enhancing the visual recognition to the surgeon as compare to the nature color of stainless steel and polymer. Further, Applicant has not disclosed that the blue dye provides an advantage, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the color as disclosed by Pedlick, and applicant's invention, to perform equally well.

21. Regarding claim 19, Pedlick discloses (Figs. 36-41 and 62-65) a method of attaching tissue to a bone in a patient's body, comprising the steps as required in claim 19 except for the step of toggling the suture anchor by pulling on the attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity. However, in column 9, lines 1-5 and lines 55-60, Pedlick discloses the suture channel, which is offset from the center of the suture anchor, allows pulling upward on the suture to firmly anchor the suture anchor in the hole. It would have been obvious to one of ordinary skill in the art to incorporate the step of pulling on the suture in an upward direction after the suture anchor is disengaged from the insertion tool to firmly secure the suture anchor into the hole.

### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731